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Esketamine for reducing perioperative opioid use in laparoscopic colorectal cancer surgery: impact on postoperative nausea and vomiting at 48 hours

Submission date
08/09/2024

Recruitment status
No longer recruiting

Registration date
26/09/2024

Overall study status
Completed

Last Edited
12/09/2024

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Colorectal cancer (CRC) is the third most common malignant tumor in the world, and surgical resection is the most effective treatment for CRC. Postoperative nausea and vomiting (PONV) is a common and painful complication after surgery. Opioids, the most commonly used intravenous analgesics for general anesthesia, are considered to be an independent risk factor for PONV, and perioperative reduction of opioid use can reduce the occurrence of PONV. Esketamine has sedative, analgesic and hypnotic effects, and is widely used in clinical anesthesia, which can completely or partially replace opioids. In this study, esketamine, an intravenous anesthetic, will be used for anesthesia and analgesia during the perioperative period of laparoscopic radical resection of colorectal cancer, partially replacing the role of opioids. By observing the occurrence of PONV in patients, the influence of opioid reduction anesthesia based on esketamine on PONV in patients undergoing laparoscopic radical resection of colorectal cancer will be evaluated, to guide clinical practice and optimize anesthesia medication plan.

Who can participate?
Patients aged between 18 and 80 years old undergoing laparoscopic radical resection of colorectal cancer

What does the study involve?
Before entering the hospital, patients were forbidden to drink for 2 h and fast for 6 h, and electrocardiogram, hematuria routine, electrolyte and related tests will be undertaken. After entering the room, the venous channel is opened routinely, and the heart rate, blood pressure, electrocardiogram and pulse oxygen saturation are monitored and oxygen is given. Anesthesia and postoperative analgesia will be performed in combination with esketamine. PONV will be actively observed, and a rating scale will be used at 1, 24 and 48 h after surgery to record the amount of postoperative relief analgesia. Venous blood will be taken before surgery, 1 h during surgery, and 1, 24 and 72 h after surgery to detect inflammation indicators. The occurrence of postoperative adverse reactions such as hallucinations or nightmares will be recorded.

What are the possible benefits and risks of participating?
The protocol of this clinical study has been reviewed by the Medical Ethics Committee of the hospital to protect the rights and interests of the subjects to the greatest extent. The research doctors will pay close attention to and deal with PONV and pain, to improve the comfort of the perioperative period to a certain extent.

The drug used in this study, esketamine hydrochloride, has been approved by the State Food and Drug Administration, and the adverse reactions are controllable. Common adverse reactions mainly include agitation, increased secretions, nausea, transient increased heart rate, transient elevated blood pressure, diplopia, dreaming, dizziness, etc., but the general degree is mild and tolerable.

Where is the study run from?
The Department of Anesthesiology at Changzhou First People's Hospital, China

When is the study starting and how long is it expected to run for?
September 2023 to September 2024

Who is funding the study?
The Department of Anesthesiology at Changzhou First People's Hospital, China. Zhao Xin, the attending doctor, was the main contact for this research and provided funds for the research.

Who is the main contact?
Zhao Xin, 644388187@qq.com

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Effect of esketamine-based opioid reduction anesthesia on postoperative nausea and vomiting in patients undergoing laparoscopic radical resection of colorectal cancer

Study objectives
In this study, esketamine was used for anesthesia and analgesia during the perioperative period of laparoscopic radical resection of colorectal cancer, partially replacing the role of opioids. By observing the occurrence of postoperative nausea and vomiting (PONV) in patients, the influence of opioid reduction anesthesia based on esketamine on PONV in patients undergoing laparoscopic radical resection of colorectal cancer was evaluated, to guide clinical practice and optimize anesthesia medication plan.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 13/09/2023, Ethics Committee of Changzhou First People's Hospital (185 Guqian Street, Tianning District, Changzhou, Jiangsu Province, 213000, China; +86 0519-68870965; xyyirb@163.com), ref: (2023) Teach No. 056

Study design
Single-center double-blind randomized controlled case study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

Hospital

Study type(s)
Efficacy

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Postoperative nausea and vomiting

Interventions
Participants will be randomly divided into two groups, the esketamine group (Group K) and the control group (Group C). The drugs required for anesthesia induction will be formulated according to the dosage in the trial protocol. Esketamine 50mg for anesthesia induction and maintenance in Group K will be diluted to 10 ml and 50 ml with normal saline, respectively, while normal saline will be used as a control in Group C.

Both groups will be given midazolam 0.05 mg/kg, propofol 1.5-2 mg/kg, and cisatracurium benzoate 0.2 mg/kg for anesthesia induction. The esketamine group (group K) will be given intravenous esketamine 0.15 mg/kg (0.03ml/kg) and sufentanil 0.2 μg/kg. The control group (group C) will be given intravenous sufentanil 0.4 μg/kg and normal saline 0.03 ml/kg.

Patients in both groups will be injected with propofol 4-8 mg/kg·h, remifentanil 0.05-0.2 μg/kg·min, and intermittent intravenous injection of cisatracurium benzoate 0.03 mg/kg as needed to maintain anesthesia. Group K will be injected with 0.15 mg/kg·h (0.15 ml/kg·h) of esketamine until 30 minutes before the end of the operation. Group C will be pumped with saline at the same rate. When SPI > 50 for more than 1min or the value increased by more than 10, sufentanil will be added 0.1μg/kg to maintain SPI: 20-50. At the same time, the pumping rate of propofol will be adjusted to maintain BIS: 40-60.

In both groups, propofol and remifentanil will be stopped and intravenous analgesia pumps connected during suture. PCIA formula Group K esketamine 1 mg/kg, sufentanil 1 μg/kg and palonosetron hydrochloride 0.25 mg, diluted to 100ml with normal saline; Group C Sufentanil 2 μg/kg, palonosetron hydrochloride 0.25mg, diluted to 100ml with normal saline. The intravenous analgesia pumps in both groups were set as follows: the first dose will be 2ml, the background dose will be 2.0 ml/h, the automatic dose will be 2ml/ time, and the locking time will be 15min.

Intervention Type
Drug

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Esketamine

Primary outcome measure

The occurrence and intensity of postoperative nausea and vomiting (PONV) measured using the PONV Impact Scale at 1, 24, and 48 h after surgery

Secondary outcome measures
1. The intraoperative dosage of opiates and propofol measured using data recorded in patient medical records throughout the procedure
2. Blood pressure, heart rate, bispectral index (BIS) value and surgical pleth index (SPI) value measured using data recorded in patient medical records collected before the operation, immediately after intubation, pneumoperitoneum establishment, 0.5h during operation, 1h during operation, 1.5h during operation, and at the end of the operation
3. Serum IL-6, IL-10, TNF-α, gastrin, motilin and substance P levels measured using ELISA in venous blood collected from patients in T0 (before surgery), T1 (1h during surgery), T2 (1h after surgery), T3 (24h after surgery) and T5 (72h after surgery)
4. The quality of postoperative recovery measured using the recovery scale QoR-15 before and 48 hours after surgery
5. Pain level at rest and exercise measured using a visual analog scale (VAS) at 1h, 24h and 48h after surgery
6. Dizziness, diplopia, hallucination or nightmare and other adverse reactions measured using data collected in patient medical records at 1h, 24h and 48h after surgery

Overall study start date
13/09/2023

Completion date
12/09/2024

Eligibility

Key inclusion criteria
1. Patients undergoing laparoscopic radical resection of colorectal cancer
2. Aged 18-80 years old, no gender limitation
3. ASA I-III
4. Postoperative agreed to use the PCIA
5. Voluntarily signed informed consent

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
96

Total final enrolment
84

Key exclusion criteria
1. People with severe consciousness disorder or mental system disease and cognitive dysfunction
2. Merge heart liver and kidney and other viscera function disorder
3. Arrhythmia (atrial fibrillation or atrioventricular conduction block between arrhythmia etc.) or after cardiac pacemaker implantation
4. BP or 180/100 MMHG, untreated or poor control of blood pressure
5. Increased intracranial pressure
6. Glaucoma
7. Without treatment, and treatment of hyperthyroidism
8. Known for esketamine injection, the active ingredient or complementary makings allergies
9. Alcohol or alcohol addiction
10. Have a vision, hearing, or language barrier and cannot communicate and cooperate

Date of first enrolment
01/10/2023

Date of final enrolment
01/08/2024

Locations

Countries of recruitment
China

Study participating centre
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Sponsor type
Government

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ROR
https://ror.org/00wgk5w17

Funder(s)

Funder type
Government

Funder Name
Changzhou Municipal Science and Technology Bureau

Alternative Name(s)
, CZST

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/10/2025

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date